

§5.71

provisions of section 505 of the Federal Food, Drug, and Cosmetic Act.

[62 FR 2556, Jan. 17, 1997, as amended at 64 FR 398, Jan. 5, 1999]

§5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under §312.44 of this chapter and in animals under §312.160 of this chapter:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under §312.44(b)(1)(viii) of this chapter:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in §312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

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(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under §511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 52 FR 7829, Mar. 13, 1987; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997]

§5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs.

The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under §312.7(d)(1) of this chapter:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

[55 FR 5445, Feb. 15, 1990, as amended at 62 FR 2556, Jan. 17, 1997]

§5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those